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(360) 651-4000 FAX (360) 651-4032 The Tulalip Tribes are the successors in interest to the Snohomish, interest to the Snohomish, in Snoqualities and Skykomish tribes and other tribes and band signatory to the Treaty of Point Elliott.

FISHERIES, WILDLIFE AND ENFORCEMENT DEPARTMENT

7615 Totem Beach Road Marysville, WA 98271

(360) 651-4480 FAX: (360) 651-4490

April 21, 1999

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

RE: Docket No. 98P-0504

Dear Sir or Madam:

This letter is in response to the petition from the Center for Science in the Public Interest (CSPI) dated June 29, 1998. The petition, Docket No. 98-0504, requests that the Food and Drug Administration (FDA) adopt regulations to control Vibrio vulnificus in molluscan shellfish.

In 1994, the State of Washington, United States Government and the Western Washington Treaty Tribes signed an agreement and consent decree governing molluscan shellfish sanitation issues. In the agreement, the unique legal and political status of the Treaty tribes was recognized. The Tribes agreed to follow the National Shellfish Sanitation Program (NSSP) Manual or subsequent documents adopted by the ISSC. In addition, the Tribe would work towards making changes through representation and issues brought forward before the Interstate Shellfish Sanitation Conference (ISSC).

The Tulalip Tribes feel that this petition should be brought forward through the ISSC and not directly to the FDA. In fact, a proposed change to the NSSP Model Ordinance was submitted to the ISSC in 1998 (Issue No. 98-106) regarding *Vibrio vulnificus* and is currently being evaluated by a committee of ISSC. The committee made recommendations to consider questions very similar to that posed by FDA in the Federal Register. There were several questions that are unanswerable at this time. Additional studies, including those conducted by FDA laboratories may provide some of the answers that would provide for a more effective control measure.

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The Tulalip Tribes request that FDA wait until the current research is complete and the ISSC process has had the opportunity to propose its scientifically based recommendation to Vibrio control. If the CSPI petition is adopted by FDA instead of going through the ISSC process, the Tulalip Tribes will need to reconsider the agreement and consent decree between the United States, Washington State and Western Washington Treaty Tribes. We appreciate the opportunity to comment on this petition and voice our concerns. Please contact our shellfish biologist, Derrick Toba, at (360) 651-4479 if you have any further comments or questions. Thank you.

Sincerely,

THE TULALIP TRIBES

Francis Sheldon

Fisheries/Wildlife/Enforcement Executive Director

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Cc: Mason Morisset, Tulalip Tribal Attorney